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Notice of Allowability	Application No.	Applicant(s)	
	10/668,487	AL-ALI ET AL.	
	Examiner	Art Unit	
	Eric F Winakur	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to _____.
2. ☒ The allowed claim(s) is/are 28-45.
3. ☒ The drawings filed on 22 September 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>112403</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with John Grover on 02 December 2004.

The application has been amended as follows:

In the specification, the priority claim (as filed 20 November 2003) has been amended to include the patent number of the parent application, as follows:

This Application is a continuation of U.S. Application No. 10/026,013, filed December 21, 2001, now U.S. Patent No. 6,714,804, which is a continuation of U.S. Application No. 09/323,176, filed May 27, 1999, now U.S. Patent No. 6,334,065, which claims priority from U.S. Provisional No. 60/087,802, filed June 3, 1998.

In the claims, claim 33 was amended as follows:

33. A method of non-invasively monitoring venous blood oxygen saturation comprising the steps of:

transmitting optical radiation through a fleshy medium having ventilator-induced pulsing blood flowing therein, the optical radiation selected so as to be attenuated by said blood;

detecting said optical radiation after attenuation through the fleshy medium;

outputting an output signal indicative of optical characteristics of the fleshy medium; and

determining venous blood oxygen saturation based upon said output signal, wherein said determining includes processing said output signal to extract ventilation-induced variations therefrom.


2. The following is an examiner's statement of reasons for allowance: Applicant cites several references related to optical measurement of blood constituents. Of particular relevance, Shiga et al. (USPN 4,927,264) teaches a method and apparatus that determines venous oxygen saturation levels by applying pressure to alter the contribution of venous components to a detected signal (see Figure 4), but does not teach or suggest extraction or analysis of ventilator-induced signals. In addition, Edgar, Jr. teaches measurement of arterial and venous oxygen saturation by applying 4 wavelengths of light to a subject, but does not detect or process ventilator-induced signals. Delpy and Mondry teach measurement of oximetry data to control operation of a ventilator, but do not teach or suggest processing ventilator-induced variations in measured signals. Further, the prior art teaches analysis of photoplethysmographic or oximetry signals to extract respiratory and heart rate information (see Oberg et al., Herczfeld et al., Yamanishi et al., and Kronberg et al.), but there is no analysis regarding ventilator-induced changes. Thus, the prior art does not teach or suggest a method that includes analysis or extraction of ventilator-induced components of a measured optical signal to determine constituent values, in combination with the other claimed steps.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571/272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Eric F Winakur
Primary Examiner
Art Unit 3736

7 December 2004